Exhibit 4

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	10/07/2013 - 11/05/2013* FEI NUMBER 3007171192

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kenneth F. Miles, Chief Compliance Officer

FIRM NAME	STREET ADDRESS
USPlabs, LLC	10761 King William Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75220-2445	Dietary Supplement Own-Label Distributor

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Your quality control personnel did not reject a dietary supplement for which a specification was not met.

Specifically, a review of your batch records revealed your contract manufacturer is relying on the ingredient supplier certificates of analyses rather than performing the analyses you require in your raw material specifications, and your quality control personnel did not reject the dietary supplements when these specifications were not met.

For example,

1. Your raw material specifications for the dietary ingredients in OxyElite Pro Advanced Formula indicates your contract manufacturer is required to conduct an identity test and "all the following tests", which include heavy metal analysis. The review of your batch record for your dietary supplement OxyElite Pro Advanced Formula, lot number 422354, revealed that your contract manufacturer's raw material specification for aegeline also lists heavy metal, including lead, arsenic, mercury and cadmium. However, your contract manufacturer is not performing these analyses; rather, your contract manufacturer is relying on the supplier's certificate of analysis for the heavy metal specification. A review of the supplier certificate of analysis revealed the certificate of analysis does not report heavy metal testing for the following raw material specifications:
   a) Your raw material specification for Aegeline, document number RMS0141, Revision #000, dated 10/8/2013, indicates your contract manufacturer is required to conduct an identity test, and the dietary ingredient "must pass the tests" listed in your specification, including heavy metal analysis prior to a lot being used in the manufacture of the dietary supplement.
   b) Your raw material specification for Olive Leave Extract Powder, document number RMS0061, Revision #001, dated 9/26/2012, indicates your contract manufacturer is required to conduct an identity test, and the dietary ingredient "must pass the tests" listed in your specification, including heavy metal analysis prior to a lot being used in the manufacture of the dietary supplement.

   Your quality control personnel reviewed, approved and released for distribution OxyElite Pro Advanced Formula, lot number 422354, on 8/26/2013.

2. Your raw material specification for Bauhinia Pruriens Extract, document number RMS0047, Revision #001, dated 9/26/2012, indicates your contract manufacturer is required to conduct an identity test, and the dietary ingredient "must pass the tests" listed in your specification. Your specification for this dietary ingredient lists identification of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jamie M. Bumpas, Investigator Elisa M. Fleming, Investigator	11/05/2013

this ingredient to be performed by TLC. However, your contract manufacturer's specification for this dietary ingredient lists "Compare w/std. Spectra", and rather than performing TLC is performing in-house FTIR. Your quality control personnel reviewed, approved and released for distribution OxyElite Pro New Formula "Purple Top", lot number 419358 on 11/13/2012.

Aegeline is a dietary ingredient in OxyElite Pro New Formula "Purple Top", OxyElite Pro Advanced Formula, OxyElite Pro Super Thermo Powder, and VERSA-1 dietary supplements. Olive Leaf Extract is a dietary ingredient in OxyElite Pro Advanced Formula. Bauhinia Pruriens Extract is a dietary ingredient in OxyElite Pro New Formula "Purple Top."

This is a repeat observation.

OBSERVATION 2

You did not establish an identity specification for each component.

Specifically, you did not establish an identity specification for the dietary ingredient Aegeline prior to use of this ingredient in the manufacture of OxyElite Pro and VERSA-1 products. Your contract manufacturer manufactures for you OxyElite Pro New Formula "Purple Top," OxyElite Pro Advanced Formula, OxyElite Pro Super Thermo Powder (all flavors), and VERSA-1 dietary supplements, all of which contain the dietary ingredient aegeline. According to the Raw Material Specification you provided during the current inspection, RMS0141, Revision #000, Effective Date 10/8/2013, you did not approve this Raw Material Specification until 10/8/2013, after the initiation of the current inspection. However, your contract manufacturer began manufacturing dietary supplements with this ingredient since at least November 2012, and since then, has manufactured for you approximately 44 lots of dietary supplements containing the aegeline prior to your approval of this Raw Material Specification.

In addition, the review of your raw material specifications found multiple dietary ingredients for which you did not establish a specification prior to the ingredient being used to manufacture your dietary supplements. The following tables lists each of the dietary ingredients for which you did not establish a specification prior to its use in a dietary supplement and the date the first lot of the dietary supplement was released.

Product	Raw Material	RM Specification Signed by QA	Rev. #
OEP Advanced	Aegeline	10/8/2013	000
	Cynanchum Auriculatum Root Extract	10/8/2013	000
	Coleus Forskolin Extract	10/8/2013	000
	Maltodextrin	10/8/2013	000

You released the first lot of OxyElite Pro Advanced on 8/2/2013, and you have released a total of 7 lots of this dietary supplement.

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Product	Raw Material	RM Specification Signed by QA	Rev. #
OEP New Formula	Aegeline	10/8/2013	000
	Hemerocallis Fulva Extract	10/8/2013	000
	Maltodextrin	10/8/2013	000

You released the first lot of OxyElite Pro New Formula "Purple Top" on 10/25/2013, and you have released a total of 22 lots of this dietary supplement.

Product	Raw Material	RM Specification Signed by QA	Rev. #
OEP STP	Aegeline	10/8/2013	000
	Oleoylethanolamide	10/8/2013	000
	Loquat Extract Powder	10/8/2013	000
	Maltodextrin	10/8/2013	000

You released the first lot of OxyElite Pro Super Thermo Powder on 2/5/2013, and you have released a total of 10 lots of this dietary supplement.

Product	Raw Material	RM Specification Signed by QA	Rev. #
VERSA-1	Aegeline	10/8/2013	000

You released the first lot of VERSA-1 on 1/9/2013, and you have released a total of six lots of this dietary supplement.

You have distributed these dietary supplements into interstate commerce.

OBSERVATION 3

You did not verify that your finished batch of dietary supplement meets product specifications for identity, purity, strength, composition, and limits on contamination that may adulterate or that may lead to adulteration of the dietary supplement.

For example,

1. Your Finished Product Specification for OxyElite Pro Advanced Formula, Document Number FPS39562, Revision #000, Effective Date 8/1/2013, lists each ingredient contained in the dietary supplement and the amount per serving; packaging information; and "Testing Criteria", including capsule weight, caffeine, heavy metals and microbiological analysis.

   Your firm produced OxyElite Pro Advanced Formula, lot number 422354 on 8/26/2013. According to your procedure as described by your QA/QC Director, upon receiving the shipment of the finished dietary supplements from your contract manufacturer, your quality control personnel complete the USPlabs Finished Product Test

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jamie M. Bumpas, Investigator Elisa M. Fleming, Investigator EMF	11/05/2013

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Record, document #QA-028-001. This test record only captures a list of criteria such as, capsule weight and capsule color, as characteristics your quality control personnel are required to verify. However, your firm did not verify the identity, purity, strength or composition of the finished dietary supplement as described in your finished product specification, nor did your firm conduct any additional analyses to determine whether or not the incoming dietary supplement met your specifications. In addition, the test record lists microbiological analysis; however, you are only relying on your contract manufacturer's incoming certificate of analysis for the results of the microbiological analysis.

Your lack of verifying finished product specifications was evident throughout all lots of OxyElite Pro and VERSA-1 dietary supplements that were produced from November 2012 to present.

2. Your SOP entitled Analytical Testing Sampling Plan, SOP #QA-030, Effective date 5/24/2012, indicates you will submit samples from incoming lots for verification testing throughout the year using "the square root of N plus one sampling rule." Since your firm put this SOP into place, you have only submitted to your contract laboratory four lots of finished product; you have submitted two lots of OxyElite Pro New Formula "Purple Top" and two lots of VERSA-1. However, this testing only analyzed theses samples for caffeine rather than identity testing for all dietary ingredients found in the finished product. You have not submitted any lots of OxyElite Super Thermo Powders or OxyElite Pro Advanced Formulas for verification testing. You have received and released for distribution a total of 38 lots of OxyElite Pro products and six lots of VERSA-1 since November 2012.

Your firm has no data or information to confirm whether these specifications were met for any of your OxyElite Pro products, including all lots produced, and VERSA-1 dietary supplements. Additionally, all of your finished product specifications for OxyElite Pro products and VERSA-1 indicate you will conduct heavy metal and pesticide analysis on a yearly basis only.

You have distributed these dietary supplements into interstate commerce.

OBSERVATION 4

Your quality control operations did not include reviewing and approving master manufacturing records.

Specifically, your quality control personnel did not review and approve a master manufacturing record (MMR) for your dietary supplement OxyElite Pro Super Thermo Powder, Blue Raspberry flavor, Revision #0.0, prior to the manufacture of the product by your contract manufacturer. The MMR you provided during the current inspection indicates your QA/QC Director reviewed and approved this MMR on 8/21/2013; however, your contract manufacturer has manufactured for you two lots (M12694-A, M12694-B) of this dietary supplement, which you reviewed, approved and released for distribution on 3/5/2013 and 2/15/2013, respectively.

Further, according to your QA/QC Director and your Chief Compliance Officer, MMRs are created by your contract manufacturer once the formula for the dietary supplement has been approved by both parties. Then, once the MMR has been created and approved by your contract manufacturer, your quality control personnel review and approve the MMR for use.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
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However, the MMR for your OxyElite Pro Super Thermo Powder, Grape Bubblegum flavor, indicates your contract manufacturer approved the MMR for use on 5/10/2013. According to the QA-036-002, Review of Master Manufacturing Record Form, Rev. #000, your QA/QC Director reviewed and approved the MMR on 4/22/2013, approximately one month prior to your contract manufacturer's approval.

This is a repeat observation.

OBSERVATION 5

Your quality control personnel approved and released for distribution a batch of dietary supplement that did not meet established product specifications.

Prior to release for distribution, you complete the finished product test record (QA-028-001), which only includes results for capsule characterization, bottle appearance, label specifications, and weight. However, this test record does not include finished product testing to ensure your dietary supplements meet your established finished product specifications for identity, purity, strength and composition for your dietary supplements.

According to your QA/QC Director, when you receive the finished product, your quality control personnel examines the finished product and reviews the batch records to ensure the finished dietary supplements meet your finished product specification in order for your dietary supplement to be released for distribution. However, according to records you provided during the current inspection, your quality control personnel have reviewed and approved for distribution into interstate commerce finished dietary supplements that did not meet your finished product specifications.

For example,

1. Your finished product specification for OxyElite Pro Advanced Formula, Document Number FPS39562, Revision #000, dated 8/1/2013, lists the strength of the dietary ingredient Yohimbe 8% Extract at 3.5 mg per serving. However, the product formula, revision #000, lists the strength of the dietary ingredient Yohimbe 8% Extract at 50.0 mg per serving, and the MMR also lists this dietary ingredient at strength of 50 mg per serving. You approved this MMR for use on 7/10/2013, and on 8/26/2013 you reviewed, approved and released lot number 422354 of OxyElite Pro Advanced Formula.

2. On 2/1/2013, your contract manufacturer manufactured for you VERSA-1, lot number N01043-A; this lot of VERSA-1 was manufactured and included an ingredient (modified starch) that was not listed on your specification, document number FPS42648. This finished product specification for VERSA-1, 30-count, Document Number FPS42648, which was approved for use on 1/7/2013, did not include modified starch as an ingredient. This batch record was reviewed and approved by your quality control personnel on 2/12/2013; however, a new finished product specification for VERSA-1, Revision #002 that includes the modified starch was not reviewed and approved by your quality control personnel until 3/18/2013. Therefore, your quality control personnel approved this dietary supplement for distribution even though it did not meet the established finished product specification.

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Furthermore, on 11/1/2013, your QA/QC Director stated that, after this batch record had been requested by FDA investigators, it was reviewed again by your quality control personnel and discovered that the dietary supplement did not meet the established finished product specification. Your QA/QC Director then explained the finished product specification for VERSA-1, Revision #002, was added to the batch record after it had already been approved, prior to providing a copy of the batch record to the FDA investigators.

Your quality control personnel reviewed and approved for distribution into interstate commerce both VERSA-1, lot number N01043-A, and OxyElite Pro Advanced Formula, lot number 422354, that did not meet your finished product specifications.

OBSERVATION 6

Your master manufacturing record did not identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to ensure that the dietary supplement is packaged and labeled as specified in the master manufacturing record.

Specifically, your master manufacturing records (MMRs) for your OxyElite Pro New Formula "Purple Top", Advanced Formula, Super Thermo Powder, and VERSA-1 dietary supplements did not identify specifications for the stages in the manufacturing process where control is necessary to ensure the quality of your dietary supplements from blending through packaging. In addition your MMRs do not establish controls and procedures to ensure each batch of dietary supplement meets your established specifications.

For the MMR for your OxyElite Pro New Formula "Purple Top", 90-count, Revision #2.0, Product Batch Record, the batch size listed is "210 M"; your QA/QC Director stated this represents 210,000 capsules. However, the Bulk Weighing Sheet and the packaging portions of the MMR do not list a batch size; rather, the packaging portion of the MMR only indicates the number of capsules per bottle (90 capsules/bottle). Therefore, the batch size listed initially on the blend portion of the MMR is not conveyed throughout the MMR to inlcude encapsulation and packaging. This MMR was approved for use by your QA/QC Director on 4/4/2013. The MMRs you provided during the current inspection list a batch size on the blend portion of the MMR, but do not list batch sizes at the encapsulation and/or packaging portions of the MMRs. Your MMRs for the OxyElite Pro and VERSA-1 dietary supplements were approved for use by your quality control personnel.

Your MMRs also lack the following required information:

- Procedures for sampling;
- Corrective action plans to use when a specification is not met;
- A statement of theoretical yield expected at each point or stage of the manufacturing process including encapsulation and packaging, and the expected yield, including the maximum and minimum percentages of theoretical yield, beyond which an investigation is necessary and a material review and disposition decision is made; and,
- Labeling:
  - OxyElite Pro Advanced Formula 90 count, 180 count, and 3-count sample size
  - OxyElite Pro New Formula "Purple Top" 180 count and 2-count sample size
  - OxyElite Pro Super Thermo Powder, Fruit Punch and Blue Raspberry, 4.6 ounce

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
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Your quality control personnel reviewed and approved for use each of your MMRs; you have received and approved for release at least 44 lots of finished dietary supplements manufactured under these MMRs.

You have distributed these dietary supplements into interstate commerce.

This is a repeat observation.

OBSERVATION 7

Your batch production records did not include documentation that the finished dietary supplement meets established specifications.

Specifically, you are not ensuring that your finished dietary supplement products meet your established specifications. In addition, you are not ensuring that your contract manufacturer meets your established finished product specifications prior to releasing product to you.

According to your QA/QC Director, your contract manufacturer provides you with a certificate of analysis (CofA), which does not meet all of your established finished product specifications. This CofA accompanies the finished product once it is released to you for distribution by your contract manufacturer. Your contract manufacturer is not conducting tests to ensure that the finished product meets your specifications for identity, purity, strength, and composition, particularly for the dietary ingredients, prior to release of the product.

For example, your finished product specifications for OxyElite Pro New Formula (90 count capsules) lists values for amounts and specifications for Caffeine Anhydrous, Aegeline, Bauhinia Extract, Higenamine HCL, Hemerocallis Fulva Extract, Yohimbe 98% extract, Maltodextrin, Silicone Dioxide, and Magnesium Stearate. Your contract manufacturer's CofA for finished OxyElite Pro New Formula product lists amounts for only the caffeine ingredient.

You have no documentation to justify why your contract manufacturer is not performing testing to ensure that the product meets specifications for identity, purity, strength and composition of the finished dietary supplements.

OBSERVATION 8

You did not establish and follow written procedures for the requirements to review and investigate a product complaint.

Specifically,

1. Your contract manufacturer did not provide details of investigations pertaining to an adverse event or severe adverse event. Your standard operating procedure QA-020, revision #005, revision date 10/29/2012, titled, "Documenting and Reporting an Adverse Event or Serious Adverse Event" Section VI.B. 7, states, "Contract manufacturer will

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review batch production and packaging records, confirm that product was manufactured to the proper specifications and all ingredient and testing criteria was met when the product was manufactured, conduct interviews with staff where appropriate and submit samples for further analysis if required." However, your "customer complaint form", which serves as your contract manufacturers investigation summary used the same following statements for 16 out of 18 of these investigation reports reviewed:

Under findings of the investigation: "Retention sample and batch record were retrieved and inspected."

Under investigation results: "All documentation and supporting release tests are within specifications. All yields, laboratory test results and finished product release criteria were met."

Of those 16 that used these statements, one was a Severe Adverse Event, QA-020-A-218.

There was no additional documentation in any of the records your firm provided for your quality control personnel to review, such as, how the retention sample was analyzed, how packaging records were reviewed, and which specifications were verified. Your quality control personnel reviewed and approved these investigations.

2. You are not following your standard operating procedure QA-020, section B. "Reporting and USPlabs Records" item 1 states "USPlabs shall document and review reported adverse events on our own QA-020-001 USPlabs LLC. Adverse event form." Section IV. "Adverse Event Information" of this form has an entry for "Follow-up Date/Actions". This entry section did not contain completed information in its paper form for any of the QA-020-001 documents reviewed. This field is intended to capture the communications log for information provided by the complainant or on behalf of the complainant, both initially and throughout the investigation.

   For example, event #QA-020-A-309, under section IV, Adverse Event Information of the QA-020-001, under the Follow-up Date/Actions is written, "CS received an email from Vitamin World on July18…"

3. Your standard operating procedure QA-020 does not include instruction on how your staff should document the description of an adverse event. Due to the lack of instruction of how to record these events, customer complaint events were inconsistent compared to what was reported by the complainant. For example, for QA-020-A-309, the description of the event on your firm's QA-020-001 form stated, "Alleges the product caused gastrointestinal discomfort." In a copy of an email provided to me by your QA/QC director that was written by your customer on behalf of the complainant, it states that the nature of the complaint was "made customer feel sick." Your QA/QC director did not know where the description of the event was obtained. Your Quality Engineer approved and closed this adverse event on 8/26/2013.

   Furthermore, there is no documentation to determine if the event description was appropriately captured. Phone call narratives between the call center service employees and complainants were not found in the written record. In addition, emails describing the event sent from the call center service or the complainant were not found in the written record.

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4. Your SOP QA-020 does not include instruction for how to address returned complaint products that are alleged to contribute to the adverse events/serious adverse events. There is no instruction on how they will be analyzed, what will be documented, how long the product will be retained, or on the final disposition of the returned item. According to your Chief Compliance Officer, the returned complaint product is retained until the investigation is closed and then it is destroyed. He also stated that the returned sample is sometimes tested if there is a serious adverse event; the product is discolored, or otherwise out of order.

   For example, for adverse event #QA-020-230, the customer returned the product. A Note to File written by your quality control personnel stated that the "Product reviewed and it matched standard." However, there was no information on when this review occurred, who conducted the review, what standards were used, and how it was compared to this standard.

This is a repeat observation.

OBSERVATION 9

You did not have records or copies of records required for product complaints readily available during the required retention period for inspection and copying by FDA when requested.

Specifically,

1. On 10/31/2013, 23 adverse event/product complaint records, and two severe adverse event reports, spanning 11/2012 to 10/31/2013, were requested for review. These records were not readily provided to FDA investigators. Product complaint cases were missing from your firm's filing system and several files were not provided until 11/1/2013. Two of the files provided on 11/1/2013, QA-020-251 and QA-020-254, had been updated and altered prior to being provided to investigators. Your QA/QC Director stated that she was reviewing and, if necessary, was updating them prior to providing them to us.

2. A Serious Adverse Event, QA-020-A-283, was initially reported to the firm on 5/22/2013. According to a narrative in the complaint file, a MedWatch form 3500A was submitted to FDA on 6/11/2013. However, there was no MedWatch Form 3500A or accompanying label in the complaint file. You did not provide investigators with this form upon request.

3. You did not have email correspondence between your call center service and emails provided directly from complainants in your complaint files. Email complaints received by your firm with the event description, date of event, and product were not maintained in the complaint files. Your Chief Compliance Officer stated repeatedly that the firm is a paper-based company and all records are maintained in paper format.

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